CHARTER
TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

AUTHORITY

Required by section 2041 of the 21st Century Cures Act, P.L. 114-255. The Task Force on Research Specific to Pregnant Women and Lactating Women (Task Force) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Task Force will provide advice and guidance to the Secretary, Department of Health and Human Services (Secretary) regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities. The Task Force will also prepare a report as described below.

DESCRIPTION OF DUTIES

In addition to providing advice and guidance to the Secretary, described above, the Task Force will, not later than 18 months after the date on which the Task Force is established, prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes the elements described below.

(1) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies;

(2) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research;

(3) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women;

(4) Identification of Federal activities, including:

(a) The state of research on pregnancy and lactation;
(b) Recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;
(c) Dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and
(d) Existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities; and

(5) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Task Force will report to the Secretary, Department of Health and Human Services.

SUPPORT

Management and support services will be provided by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Task Force, including compensation and travel expenses for members, but excluding staff support, is $119,436. The estimate of annual person-years of staff support required is 2.00 at an estimated annual cost of $310,000.

DESIGNATED FEDERAL OFFICER

The Director, NICHD, will assign a full-time or permanent part-time NICHD employee as the Designated Federal Officer (DFO) of the Task Force. In the event that the DFO cannot fulfill the assigned duties of the committee, one or more full-time or permanent part-time NICHD or NIH employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the committee's and subcommittees' meetings, prepare and approve all meeting agendas, attend all committee and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH or the Director, NICHD.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Task Force will be held not less than two times each year or more frequently, as appropriate to fulfill its duties. All meetings of the Task Force will be open to the public

except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

DURATION

The Task Force will terminate on the date that is two years after the date on which the Task Force is established. The Secretary may extend the operation of the Task Force for one additional two year period if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the Task Force on Research Specific to Pregnant Women and Lactating Women will expire two years from the date the Charter is filed.

MEMBERSHIP AND DESIGNATION

The Task Force will be composed of both Federal and non-Federal members. All members serve for the duration of the committee.

Federal Members – The Task Force will include the following Federal members or the designees of such members:

The Director of the Centers for Disease Control and Prevention;
The Director of the National Institutes of Health;
The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development;
The directors of such other appropriate national research institutes of the National Institutes of Health;
The Commissioner of Food and Drugs;
The Director of the Office on Women's Health;
The Director of the National Vaccine Program Office;
The Secretary, Department of Veterans Affairs;
The Secretary, Department of Defense;
The Director of the Agency for Healthcare Research and Quality;
The Administrator of the Health Resources and Services Administration; and

The head of any other research-related agency or department not described above that the Secretary determines appropriate.

Non-Federal Members – The Task Force will be composed of each of the following non-Federal members:

Representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;
Nonprofit organizations with expertise related to the health of women and children;
Relevant industry representatives; and
Other representatives, as appropriate.

Non-Federal members will compose not more than one-half, and not less than one-third, of the total membership of the Task Force. The Secretary will appoint all non-Federal members. All non-Federal members serve as Special Government Employees. None of these members serve as Representatives.

A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

The Chair of the Committee will be a Federal official selected by the Secretary, HHS and will serve the duration of the Committee.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Task Force's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants and ex officio members do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Task Force and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These

records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE (Establishment)

March 13, 2017

APPROVED

3/8/2017
Date

Director